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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/127,411	07/31/98	GRUENBERG	

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EXAMINER	
SCHWADRON, R	
ART UNIT	PAPER NUMBER

1644  
DATE MAILED:

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05/08/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
09/127,411

Applicant(s)

Gruenberg

Examiner  
Ron Schwadron, Ph.D.

Group Art Unit  
1644

- ☐ Responsive to communication(s) filed on \_\_\_\_\_
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

- ☒ Claim(s) 36-40 and 154-157 is/are pending in the application.
- Of the above, claim(s) 36, 38, 40, and 154-157 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 37 and 39 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☒ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- ☒ Notice of References Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Applicant's election with traverse of the invention of the species of claims 37 and 39 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that are stated in said paper. This is not found persuasive because of the following reasons. Regarding applicants comments, claim 37 states that in order to produce Th1 that CD4+ cells are treated with an activating agent that produces a population of cells that is predominantly Th1. Thus, the two methods differ in that one is a method of producing CD4 cells and one is a method of producing Th1 wherein the two methods are different because claim 37 states that in order to produce Th1 that CD4+ cells are treated with an activating agent that produces a population of cells that is predominantly Th1. Regarding the methods of claims 39 and 40, said claims recite the use of different reagents (eg. antiCD3 versus antiCD28 antibody). It would require an undue burden on the Examiner to search additional nonelected species. The requirement is still deemed proper and is therefore made FINAL. Claim 39 has been included because said method would result in the production of Th1 cells.
2. Claims 36,38,40,154-157 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected species, the requirement having been traversed in Paper No. 8.
3. Claims 37 and 39 are under consideration.
4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because of the following reasons. There were two different defective declarations filed with the instant application. The first declaration is defective because it is unsigned and because it claims priority to itself under 35 USC 120. The second declaration is defective because it does not list the application number of the PCT to which priority under U.S.C. 120 is desired.
5. Regarding the priority data disclosed in the specification, page 1, second paragraph, the address of applicants' attorney's law firm was erroneously placed in the middle of a sentence

related to the priority claim to PCT/US96/12170. This information should be deleted.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 37 and 39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification for the recitation of "isolating mononuclear cells" in claim 37 (said language is actually recited in nonelected claim 36 upon which claim 37 depends). The original claims disclose the claimed method wherein the claim recites "isolating CD4+ mononuclear cells", but not the claimed invention which recites "isolating mononuclear cells". There is no disclosure in the specification as originally filed of the scope of the claimed invention (eg. it constitutes new matter).

8. Claims 37 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 37 and 39 are indefinite in that they depend on nonelected claim 36.

9. Regarding priority for the claimed inventions with regards to the application of prior art, the claimed inventions are not disclosed in parent application provisional application 60/044693 (the application formerly known as 08/506668), and therefore priority with regards to the application of prior art is taken as the filing date of parent application 08/700565 to which applicant claims priority.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness

rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 37 and 39 are rejected under 35 U.S.C. § 103 as being unpatentable over Babbitt et al. (US Patent 5,766,920) in view of Carew (US Patent 5,123,901) and Nabel.


Babbitt et al. teach methods for producing Th1 cells, wherein patient mononuclear cells are removed, activated and expanded in vitro (see columns 5 and 6). The method taught by Babbitt et al. uses IFN  $\gamma$  enriched supernatants and OKT3 (eg. antiCD3 antibody) to produce Th1 populations (see columns 5 and 6). Babbitt et al. teach that autologous expanded Th1 cells are reinfused to treat HIV (see column 7). The cells are expanded to clinically relevant numbers (see column 19). Babbitt et al. do not teach that HIV negative Th1 are selected after activation. Nabel teaches that T cell activation results in production of HIV virus in latently infected T cells (see Abstract). Carew teaches that HIV positive T cells can be removed from blood or a fluid containing said infected cells by treatment with immunoreactive beads coated with a reagent that binds HIV (see Abstract and column 2, last paragraph). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Babbitt et al. teach methods for producing Th1 cells from HIV infected patients, wherein patient mononuclear cells are removed, activated and expanded in vitro, Nabel teaches that T cell activation results in production of HIV virus in latently infected T cells and Carew teaches that HIV positive T cells can be removed from blood or a fluid containing said infected cells by treatment with immunoreactive beads coated with a reagent that binds HIV. One of ordinary skill in the art would have been motivated to do the aforementioned because Carew teaches that HIV infected T cells should be removed from blood products that are administered to humans (see abstract).

12. No claim is allowed.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official

Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

 **RONALD B. SCHWADRON**  
**PRIMARY EXAMINER**  
**GROUP 1600 (600)**

Ron Schwadron, Ph.D.  
Primary Examiner  
Art Unit 1644